



DEPARTMENT OF HEALTH AND HUMAN SERVICE

Southwest Region

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Food and Drug Administration
Denver District Office
Bldg. 20-Denver Federal Center
P.O. Box 25087
6th Avenue & Kipling Street
Denver, Colorado 80225-0087
Telephone: 303-236-3000
FAX: 303-236-3100

July 15, 2002

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Ref. # DEN-02-15

Mr. Bruce F. Shrutt, President
Altamira Ltd.
3800 Dahlia Street
Denver, Colorado 80207

Dear Mr. Shrutt:

We inspected your firm, located at the above address, on May 28 and 30, 2002 and found that you have serious deviations from the Seafood HACCP regulations [Title 21 Code of Federal Regulations, Part 21 (21 CFR Part 123)]. The deviations we found cause your refrigerated ready to eat seafood products such as seafood salads, vacuum packaged smoked mussels, and herring to be in violation of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (the Act). You can find the Seafood HACCP regulations through links in FDA's home page at www.fda.gov.

The deviations are as follows:

You must have a written HACCP plan to control any food safety hazards that are reasonably likely to occur, to comply with 21 CFR 123.6(b). However, your firm does not have a HACCP plan for refrigerated ready to eat seafood and seafood salads to control the food safety hazard of foodborne pathogens. We advised you of this requirement during our inspections of February 22, 2001 and May 28 and 30, 2002, and via our letter of May 24, 2001.

You must adequately monitor sanitation conditions and practices during storage, to comply with 21 CFR 123.11(b). However, your firm did not monitor: maintenance of toilet facilities; protection of food packaging material from adulteration with lubricants, fuel, pesticides, cleaning compounds, sanitizing agents, condensate, and other

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chemical, physical, and biological contaminants; proper labeling, storage, and use of toxic compounds; control of employee health conditions that could result in the microbial contamination of food packaging materials; and exclusion of pests from the food plant. Your firm has no system in place to monitor the above conditions. You were advised of this requirement during our inspections of February 22, 2001 and May 28 and 30, 2002.

Also, please be advised that you are required by 21 CFR 123.11(b) to have someone adequately trained in HACCP or an otherwise qualified individual to develop, reassess and modify your HACCP plan and perform record review. You were advised of this requirement during our inspections of February 22, 2001 and May 28 and 30, 2002, and via our letter of May 24, 2001.

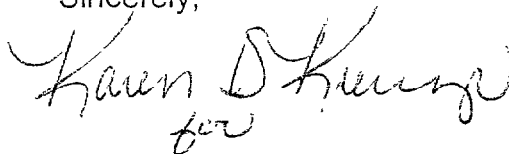
We may take further action if you do not promptly correct these violations. For instance, we may take action to seize your product(s) and/or enjoin your firm from operating.

Please respond in writing within three (3) weeks from your receipt of this letter. Your response should outline the specific things you are doing to correct these deviations. You may wish to include in your response, documentation such as your HACCP Plan, how you plan to monitor applicable sanitation conditions, or other useful information that would assist us in evaluating your corrections. If you cannot complete all corrections before you respond, we expect that you will explain the reason for your delay and state when you will correct any remaining deviations.

This letter may not list all the deviations at your facility. You are responsible for ensuring that your processing plant operates in compliance with the Act, the Seafood HACCP regulations and the Good Manufacturing Practice regulations (21 CFR Part 110). You also have a responsibility to use procedures to prevent further violations of the Federal Food, Drug, and Cosmetic Act and all applicable regulations.

Please send your reply to the Food and Drug Administration, Attention: Shelly L. Maifarth, Compliance Officer, at the above letterhead address. If you have questions regarding any issue in this letter, please contact Ms. Maifarth at (303) 236-2046.

Sincerely,

A handwritten signature in cursive script, appearing to read "Karen D. Collins", with the word "for" written below it in a smaller, simpler script.

B. Belinda Collins
District Director

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